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| Substitute Form PTO-1449<br>(Modified)  | U.S. Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br>17738-003001 | Application No.<br>10/728,195 |
| <b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary) |  | Applicant<br>Lu et al.                |                               |
|   |  | Filing Date<br>December 3, 2003       | Group Art Unit<br>1648        |
| (37 CFR § 1.98(b))  |  |                                       |                               |

## U.S. Patent Documents

| Examiner<br>Initial | Desig.<br>ID | Document<br>Number | Publication<br>Date | Patentee | Class | Subclass | Filing Date<br>If Appropriate |
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## Foreign Patent Documents or Published Foreign Patent Applications

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|                     |              |                    |                     |                             |       |          | Yes         | No |
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## Other Documents (include Author, Title, Date, and Place of Publication)

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|---------------------|--------------|---|
| /B,P./              | C1           | Alonso et al., "Biodegradable microspheres as controlled-release tetanus toxoid delivery systems," Vaccine 12:299-306 (1994)  |
|                     | C2           | Bagarazzi et al., "Nucleic acid-based vaccines as an approach to immunization against human immunodeficiency virus type-1," Curr. Top Microbiol. Immunol. 226:107-43 (1998)   |
|                     | C3           | Barnett et al., "The ability of an oligomeric human immunodeficiency virus type 1 (HIV-1) envelope antigen to elicit neutralizing antibodies against primary HIV-1 isolates is improved following partial deletion of the second hypervariable region," J. Virol. 75:5526-40 (2001) |
|                     | C4           | Barouch et al., "Eventual AIDS vaccine failure in a rhesus monkey by viral escape from cytotoxic T lymphocytes," Nature 415(6869):335-9 (2002)  |
|                     | C5           | Boyer et al., "Protection of chimpanzees from high-dose heterologous HIV-1 challenge by DNA vaccination," Nat. Med. 3(5):526-32 (1997)  |
|                     | C6           | Chakrabarti et al., "Modifications of the human immunodeficiency virus envelope glycoprotein enhance immunogenicity for genetic immunization," J. Virol. 76(11):5357-68 (2002)  |
|                     | C7           | Chapman, et al., "Effect of intron A from human cytomegalovirus (Towne) immediate-early gene on heterologous expression in mammalian cells," Nucleic Acids Res. 19:3979-3986 (1991)   |
|                     | C8           | Clements et al., "Cross-protective immune responses induced in rhesus macaques by immunization with attenuated macrophage-tropic simian immunodeficiency virus," J. Virol. 69: 2737 (1995)  |
|                     | C9           | Cristillo et al., "Preclinical evaluation of cellular immune responses elicited by a polyvalent DNA prime/protein boost HIV-1 vaccine," Virology 346(1):151-68 (2006)   |
|                     | C10          | Eldridge et al., "Biodegradable microspheres as a vaccine delivery system," Molec. Immunol. 28:287-94 (1991)  |
|                     | C11          | Goulder et al., "Evolution and transmission of stable CTL escape mutations in HIV infection," Nature 412:334-338 (2001)   |
|                     | C12          | Goulder et al., "Late escape from an immunodominant cytotoxic T-lymphocyte response associated with progression to AIDS," Nature Med. 3:212-217 (1997)  |
|                     | C13          | Hu et al., "The immunostimulating complex (ISCOM) is an efficient mucosal delivery system for respiratory syncytial virus (RSV) envelope antigens inducing high local and systemic antibody responses," Clin. Exp. Immunol. 113:235-43 (1998)                                       |
|                     | C14          | Hurwitz et al., "Application of the polyvalent approach to HIV-1 vaccine development," Curr. Drug Targets Infect. Disord. 5(2) 143-56 (2005)  |

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|--|-----------------|
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|---------------------|--------------|---|
| B.F.J.              | C15          | Johnston and Flores, "Progress in HIV vaccine development," Curr. Op. In. Pharmac. 1:504-510 (2001)   |
| ↓                   | C16          | Jones et al., "Protection of mice from Bordetella pertussis respiratory infection using microencapsulated pertussis fimbriae," Vaccine 13(7):675-81 (1995)    |
|                     | C17          | Kensil, et al., "QS-21 and QS-7: purified saponin adjuvants," Dev. Biol. Stand. 92:41-7 (1998)  |
|                     | C18          | Kong et al., "Immunogenicity of multiple gene and clade human immunodeficiency virus type 1 DNA vaccines," J. Virol. 77:12764-772 (2003)                      |
|                     | C19          | Letvin et al., "Immunogenicity of multiple gene and clade human immunodeficiency virus type 1 DNA vaccines," Proc. Natl. Acad. Sci. USA 94(17):9378-83 (1997) |
|                     | C20          |   |

|  |                 |
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| /B.P./           | C20       | Ljungberg et al., "Enhanced immune responses after DNA vaccination with combined envelope genes from different HIV-1 subtypes," <i>Virology</i> 302(1):44-57 (2002)  |
|                  | C21       | Lu et al., "Immunogenicity of DNA vaccines expressing human immunodeficiency virus type 1 envelope glycoprotein with and without deletions in the V1/2 and V3 regions," <i>AIDS Res. Hum. Retroviruses</i> 14(2):151-5 (1998)  |
|                  | C22       | Lu et al., "Simian immunodeficiency virus DNA vaccine trial in macaques," <i>J. Virol.</i> 70(6):3978-991 (1996)   |
|                  | C23       | MacGregor et al., "First human trial of a DNA-based vaccine for treatment of human immunodeficiency virus type 1 infection: safety and host response," <i>J. Infect. Dis.</i> 178(1):92-100 (1998)   |
|                  | C24       | Mascola et al., "Immunization with envelope subunit vaccine products elicits neutralizing antibodies against laboratory-adapted but not primary isolates of human immunodeficiency virus type 1. The National Institute of Allergy and Infectious Diseases AIDS Vaccine Evaluation Group," <i>J. Infect. Dis.</i> 173:340-348 (1996) |
|                  | C25       | Mascola et al., "Human immunodeficiency virus type 1 neutralization measured by flow cytometric quantitation of single-round infection of primary human T cells," <i>J. Virol.</i> 76(10):4810-21 (2002)   |
|                  | C26       | McMichael and Hanke, "The quest for an AIDS vaccine: is the CD8+ T-cell approach feasible?" <i>Nat. Rev. Immunol.</i> 2(4):283-91 (2002)   |
|                  | C27       | Montefiori et al., "Evaluation of antiviral drugs and neutralizing antibodies to human immunodeficiency virus by a rapid and sensitive microtiter infection assay," <i>J. Clin. Microbiol.</i> 26:231-237 (1988)   |
|                  | C28       | Pal et al., "Immunization of rhesus macaques with a polyvalent DNA prime/protein boost human immunodeficiency virus type 1 vaccine elicits protective antibody response against simian human immunodeficiency virus of R5 phenotype," <i>Virology</i> (2006 Feb 2)   |
|                  | C29       | Qiu, et al., "Enhancement of primary and secondary cellular immune responses against human immunodeficiency virus type 1 gag by using DNA expression vectors that target Gag antigen to the secretory pathway," <i>J. Virology</i> 74(13):5997-6005 (2000)   |
| ↓                | C30       | Rencher and Hurwitz, "Effect of natural HIV-1 envelope V1-V2 sequence diversity on the binding of V3-specific and non-V3-specific antibodies," <i>J. Acquir. Immune Defic. Syndr. Hum. Retrovirol.</i> 16(2):69-73 (1997)  |

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| /B.P./           | C31       | Rencher et al., "Does the key to a successful HIV type 1 vaccine lie among the envelope sequences of infected individuals?" AIDS Res. Hum. Retroviruses 11(9):1131-3 (1995)   |
|                  | C32       | Richmond et al., "Screening of HIV-1 Env glycoproteins for the ability to raise neutralizing antibody using DNA immunization and recombinant vaccinia virus boosting," Virology 230(2):265-74 (1997)  |
|                  | C33       | Robinson, "DNA vaccines for immunodeficiency viruses," AIDS 11(Suppl A):S109-19 (1997)  |
|                  | C34       | Stambas et al., "Long lived multi-isotype anti-HIV antibody responses following a prime-double boost immunization strategy," Vaccine 23(19):2454-64 (2005)  |
|                  | C35       | Takahashi et al., "Induction of CD8+ cytotoxic T cells by immunization with purified HIV-1 envelope protein in ISCOMs," Nature 344:873-75 (1990)  |
|                  | C36       | Vitiello et al., "Development of a lipopeptide-based therapeutic vaccine to treat chronic HBV infection. I. Induction of a primary cytotoxic T lymphocyte response in humans," J. Clin. Invest. 95:341-49 (1995)  |
|                  | C37       | Wang et al., "Polyvalent HIV-1 Env vaccine formulations delivered by the DNA priming plus protein boosting approach are effective in generating neutralizing antibodies against primary human immunodeficiency virus type 1 isolates from subtypes A, B, C, D and E," Virology (2006 Apr 6) |
| ↓                | C38       | Weber et al., "Neutralization serotypes of human immunodeficiency virus type 1 field isolates are not predicted by genetic subtype. The WHO Network for HIV Isolation and Characterization," Virol. 70: 7827-832 (1996)   |
|                  | C39       |   |
|                  | C40       |   |

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| /B.P./           | C40       | Zhan et al., "Minor components of a multi-envelope HIV vaccine are recognized by type-specific T-helper cells," Vaccine 22(9-10):1206-13 (2004)                      |
| /B.P./           | C41       | Zolla-Pazner et al., "Immunotyping of human immunodeficiency virus type 1 (HIV): an approach to immunologic classification of HIV," J. Virol. 73: 4042-51 (1999)     |
| /B.P./           | C42       | HIV Vaccine Development Status Report, May 2000, <a href="http://niaid.gov/daids/vaccine/whsummarystatus.htm">http://niaid.gov/daids/vaccine/whsummarystatus.htm</a> |
|                  | C43       |  |

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